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PTO/SB/21 (04-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/728,521-Conf. #8270
	Filing Date	December 5, 2003
	First Named Inventor	Atul Varadhachary
	Art Unit	N/A
	Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	Attorney Docket Number	HO-P02703US2

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below):  Return Receipt Postcard 3 References
<b>Remarks</b>		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

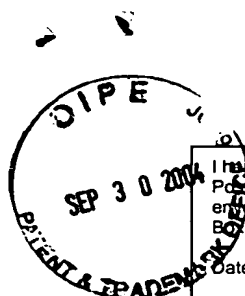
Firm or Individual name	FULBRIGHT & JAWORSKI L.L.P. Melissa W. Acosta - 45,872
Signature	
Date	September 30, 2004

**Transmittal**

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. ER 147056393 US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

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Dated: September 30, 2004 Signature:

*Annette Devereux*  
(Annette Devereux)

Docket No.: HO-P02703US2  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Atul Varadhachary et al.

Application No.: 10/728,521

Confirmation No.: 8270

Filed: December 5, 2003

Art Unit: N/A

For: ORAL LACTOFERRIN IN THE  
TREATMENT OF SEPSIS

Examiner: Not Yet Assigned

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 CFR 1.97, Applicant(s) hereby make of record the following additional documents. A PTO Form SB/08 and a full copy of each of these documents accompany this statement.

Applicant(s) have become aware of the following documents, cited in an International Search Report issued August 2, 2004, during the prosecution of international application no. PCT/US03/38621, which corresponds to the above referenced application, and in accordance with 37 CFR 1.97(c) and (e)(1) or (b)(3), hereby submit(s) these documents for the Examiner's consideration. These documents are cited on the enclosed PTO Form SB/08, and a copy of the International Search Report and each document cited thereon are enclosed as well.

This statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any document herein be construed *per se* as a representation that such document is prior art. Moreover, Applicant(s) understand(s) the Examiner will make an independent evaluation of the cited documents.

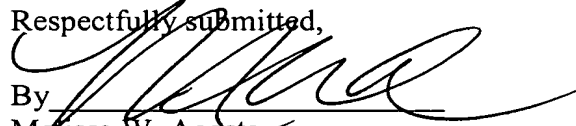
The undersigned hereby certifies that each item contained in this Supplemental Information Disclosure Statement was cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 06-2375, under Order No. HO-P02703US2. A duplicate copy of this paper is enclosed.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02703US2 from which the undersigned is authorized to draw.

Dated: September 30, 2004

Respectfully submitted,



By  
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<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>		
				Application Number	10/728,521	
				Filing Date	December 5, 2003	
				First Named Inventor	Atul Varadhachary	
				Art Unit	N/A	
				Examiner Name	Not Yet Assigned	
Sheet	1	of	-	1	Attorney Docket Number	HO-P02703US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US-5,240,909	08-31-1993	Nitsche	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)					

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See attached Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	Kruzel et al, "Lactoferrin and insult induced metabolic imbalance in humans and other animals," International Congress Series 2000, 1195, pgs 301 -310.	
	CB	McClead et al, "Oral Lactoferrin and Lactoperoxidase decrease Mortality of Enterotoxigenic E coli. Infention," Pediatric Research 1987, Vol. 21, No. 4 Part 2, pp 417A.	
	CC	Lee et al, "The Protective Effects of Lactoferrin Feeding against Endotoxin Lethal Shock in Germfree Piglets," Infection and Immunity Vol. 66 No. 4, 1998, pgs 1421-1426.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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Application No. (if known): 10/728,521

Attorney Docket No.: HO-P02703US2

## Certificate of Express Mailing Under 37 CFR 1.10

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IDS (Citation) by Applicant